ISO 17025 Requirements with No Equivalent NELAC Sections

The following text appears double-underlined in the proposed NELAC Chapter 5 with ISO 17025 standard.

5.4 Management requirements

5.4.1 Organization

5.4.1.4 If the laboratory is part of an organization performing activities other than environmental testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the environmental testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest. **(17025: 4.1.4)**

a) Where a laboratory is part of a larger organization, the organizational arrangements shall be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this Standard. **(17025: 4.1.4)**

b) The laboratory must be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment. All environmental testing or calibration laboratories shall not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its environmental testing or calibration activities. **(17025: 4.1.4)**

5.4.1.5 The laboratory shall: **(NELAC: 5.4.2)**

e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services; **(17025: 4.1.5.e)**

5.4.3 Document control

5.4.3.1 General

The laboratory shall establish and maintain procedures to control all documents that form part of its quality system (internally generated or from external sources), such as regulations, standards, other normative documents, environmental test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals. **(17025: 4.3.1)**

"Documents" include policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written. **(17025: 4.3.1)**

The control of data related to environmental testing and calibration is covered in 5.5.4.7. The control of records is covered in 5.4.12. **(17025: 4.3.1)**

5.4.3.2 Document approval and issue

5.4.3.2.1 All documents issued to personnel in the laboratory as part of the quality system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the

quality system shall be established and be readily available to preclude the use of invalid and/or obsolete documents. **(17025: 4.3.2.1)**

5.4.3.2.2 The procedure(s) adopted shall ensure that: **(17025: 4.3.2.2)**

a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed; **(17025: 4.3.2.2.a)**

b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements; **(17025: 4.3.2.2.b)**

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; **(17025: 4.3.2.2.c)**

d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked. **(17025: 4.3.2.2.d)**

5.4.3.2.3 Quality system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies). **(17025: 4.3.2.3)**

5.4.3.3 Document changes

5.4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval. **(17025: 4.3.3.1)**

5.4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments. **(17025: 4.3.3.2)**

5.4.3.3.3 If the laboratory's documentation control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable. **(17025: 4.3.3.3)**

5.4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled. **(17025: 4.3.3.4)**

5.4.4 Review of requests, tenders and contracts

5.4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for environmental testing and/or calibration shall ensure that: **(17025: 4.4.1)**

a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.5.4.2); **(17025: 4.4.1.a)**

b) the laboratory has the capability and resources to meet the requirements; **(17025: 4.4.1.b)**

The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the environmental tests and/or calibrations in question. The review may also

encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial environmental test or calibration programs using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc. **(17025: 4.4.1.c)**

c) the appropriate environmental test and/or calibration method is selected and capable of meeting the clients' requirements (see 5.5.4.2). **(17025: 4.4.1.c)**

Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the client. **(17025: 4.4.1.c)**

A contract may be any written or oral agreement to provide a client with environmental testing and/or calibration services. **(17025: 4.4.1.c)**

5.4.4.2 Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract. **(17025: 4.4.2)**

For review of routine and other simple tasks, the date and the identification (e. g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced environmental testing and/or calibration tasks, a more comprehensive record should be maintained. **(17025: 4.4.2)**

5.4.4.3 The review shall also cover any work that is subcontracted by the laboratory. **(17025: 4.4.3)**

5.4.4.4 The client shall be informed of any deviation from the contract. **(17025: 4.4.4)**

5.4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel. **(17025: 4.4.5)**

5.4.5 Subcontracting of environmental tests and calibrations

5.4.5.3 The laboratory is responsible to the client for the subcontractor’s work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used. **(17025: 4.5.3)**

5.4.6 Purchasing services and supplies

5.4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the environmental tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the environmental tests and calibrations. **(17025: 4.6.1)**

5.4.7 Service to the client

The laboratory shall afford clients or their representatives cooperation to clarify the client's request and to monitor the laboratory’s performance in relation to the work performed, provided that the laboratory ensures confidentiality to other clients. **(17025: 4.7)**

5.4.9 Control of nonconforming environmental testing and/or calibration work

5.4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its environmental testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the client. The policy and procedures shall ensure that: **(17025: 4.9.1)**

a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified; **(17025: 4.9.1.a)**

b) an evaluation of the significance of the nonconforming work is made; **(17025: 4.9.1.b)**

c) corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work; **(17025: 4.9.1.c)**

d) where necessary, the client is notified and work is recalled; **(17025: 4.9.1.d)**

e) the responsibility for authorizing the resumption of work is defined. **(17025: 4.9.1.c)**

5.4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 5.4.10 shall be promptly followed. **(17025: 4.9.2)**

5.4.10 Corrective action

5.4.10.1 General

The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified. **(17025: 4.10.1)**

5.4.10.2 Cause analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem. **(17025: 4.10.2)**

5.4.10.3 Selection and implementation of corrective actions

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. **(17025: 4.10.3)**

Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem. **(17025: 4.10.3)**

The laboratory shall document and implement any required changes resulting from corrective action investigations. **(17025: 4.10.3)**

5.4.10.4 Monitoring of corrective actions

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective. **(17025: 4.10.4)**

5.4.10.5 Additional audits

Where the identification of nonconformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 5.4.13 as soon as possible. **(17025: 4.10.5)**

5.4.11 Preventive action

Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints. **(17025: 4.11.2)**

5.4.11.1 Needed improvements and potential sources of nonconformances, either technical or concerning the quality system, shall be identified. If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformances and to take advantage of the opportunities for improvement. **(17025: 4.11.1)**

5.4.11.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective. **(17025: 4.11.2)**

5.4.12 Control of records

5.4.12.1 General

5.4.12.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions. **(17025: 4.12.1.1)** Records may be in any media, such as hard copy or electronic media. **(17025: 4.12.1.2)**

5.4.12.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established. **(17025: 4.12.1.2)**

5.4.12.1.3 All records shall be held secure and in confidence. **(17025: 4.12.1.3)**

5.4.12.1.4 The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records. **(17025: 4.12.1.4)**

5.4.12.2 Technical records

5.4.12.2.1 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each environmental test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the environmental test or calibration to be repeated under conditions as close as possible

to the original. The records shall include the identity of personnel responsible for the sampling, performance of each environmental test and/or calibration and checking of results. **(17025: 4.12.2.1)**

5.4.12.2.2 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task. **(17025: 4.12.2.2)**

5.4.12.2.3 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data. **(17025: 4.12.2.3)**

5.4.13 Internal audits

5.4.13.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken. **(17025: 4.13.4)**

5.5 Technical requirements

5.5.1 General

5.5.1.1 Many factors determine the correctness and reliability of the environmental tests and/or calibrations performed by a laboratory. These factors include contributions from:

- human factors (5.5.2);
- accommodation and environmental conditions (5.5.3);
- environmental test and calibration methods and method validation (5.5.4);
- equipment (5.5.5);
- measurement traceability (5.5.6);
- sampling (5.5.7);
- the handling of samples (5.5.8). **(17025: 5.1.1)**

5.5.1.2 The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) environmental tests and between (types of) calibrations. The laboratory shall take account of these factors in developing environmental test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses. **(17025: 5.1.2)**

5.5.2 Personnel

5.5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory. **(17025: 5.2.2)**

5.5.2.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system. **(17025: 5.2.3)**

5.5.4 Environmental test and calibration methods and method validation

5.5.4.2 Selection of methods

The laboratory shall use environmental test and/or calibration methods, including methods for sampling, which meet the needs of the client and which are appropriate for the environmental tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application. **(17025: 5.4.2)**

When the client does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The client shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate standard methods before introducing the environmental tests or calibrations. If the standard method changes, the confirmation shall be repeated. **(17025: 5.4.2)**

The laboratory shall inform the client when the method proposed by the client is considered to be inappropriate or out of date. **(17025: 5.4.2)**

5.5.4.3 Laboratory-developed methods

The introduction of environmental test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources. **(17025: 5.4.3)**

Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured. **(17025: 5.4.3)**

5.5.4.4 Non-standard methods

When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the environmental test and/or calibration. The method developed shall have been validated appropriately before use. **(17025: 5.4.4)**

5.5.4.5 Validation of methods

5.5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. **(17025: 5.4.5.1)**

5.5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use. **(17025: 5.4.5.2)**

5.5.4.5.3 The range and accuracy of the values obtainable from validated methods (e. g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the clients' needs. **(17025: 5.4.5.3)**

5.5.4.6 Estimation of uncertainty of measurement

5.5.4.6.1 A calibration laboratory, or an environmental testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations. **(17025: 5.4.6.1)**

5.5.4.6.2 Environmental testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data. **(17025: 5.4.6.2)**

In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.5.10). **(17025: 5.4.6.2)**

5.5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis. **(17025: 5.4.6.3)**

5.5.5 Equipment

5.5.5.4 Each item of equipment and its software used for environmental testing and calibration and significant to the result shall, when practicable, be uniquely identified. **(17025: 5.5.4)**

5.5.5.5 The records shall include at least the following: **(17025: 5.5.5)**

c) checks that equipment complies with the specification (see 5.5.5.2); **(17025: 5.5.5.c)**

5.5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration. **(17025: 5.5.6)**

5.5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service. **(17025: 5.5.9)**

5.5.5.11 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e. g. in computer software) are correctly updated. **(17025: 5.5.11)**

5.5.5.12 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results. **(17025: 5.5.12)**

5.5.6 Measurement traceability

5.5.6.2 Specific requirements

5.5.6.2.1 Calibration laboratories

5.5.6.2.1.1 For calibration laboratories, the program for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI). **(17025: 5.6.2.1.1)**

A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.5.10.4.2). (**17025: 5.6.2.1.1)**

5.5.6.2.1.2 There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

- the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;
- the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned. **(17025: 5.6.2.1.2)**

Participation in a suitable program of interlaboratory comparisons is required where possible. **(17025: 5.6.2.1.2)**

5.5.6.2.2 Testing laboratories

5.5.6.2.2.1 For testing laboratories, the requirements given in 5.5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed. **(17025: 5.6.2.2.1)**

5.5.6.3 Reference standards and reference materials

5.5.6.3.3 Intermediate checks

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules. **(17025: 5.6.3.3)**

5.5.6.3.4 Transport and storage

The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity. **(17025: 5.6.3.4)**

5.5.7 Sampling

5.5.7.2 Where the client requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing environmental test and/or calibration results, and shall be communicated to the appropriate personnel. **(17025: 5.7.2)**

5.5.7.3 The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the environmental testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon. **(17025: 5.7.3)**

5.5.8 Handling of samples

5.5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of samples, including all provisions necessary to protect the integrity of the sample, and to protect the interests of the laboratory and the client. **(17025: 5.8.1)**

5.5.8.3 Upon receipt of the samples, the condition, including any **(NELAC: 5.11.3.a)** abnormalities or departures from normal or specified conditions, as described in the environmental test or calibration method, shall be recorded. When there is doubt as to the suitability of a sample for environmental test or calibration, or when a sample does not conform to the description provided, or the environmental test or calibration required is not specified in sufficient detail, the laboratory shall consult the client for further instructions before proceeding and shall record the discussion. **(17025: 5.8.3)**

5.5.10.3 Test reports

5.5.10.3.1 In addition to the requirements listed in 5.5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following: **(17025: 5.10.3.1)**

d) where appropriate and needed, opinions and interpretations (see 5.5.10.5); **(17025: 5.10.3.1.d)**

e) additional information which may be required by specific methods, clients or groups of clients. **(17025: 5.10.3.1.e)**

5.5.10.3.2 In addition to the requirements listed in 5.5.10.2 and 5.5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results: **(17025: 5.10.3.2)**

a) the date of sampling; **(17025: 5.10.3.2.a)**

b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate); **(17025: 5.10.3.2.b)**

c) the location of sampling, including any diagrams, sketches or photographs; **(17025: 5.10.3.2.c)**

d) a reference to the sampling plan and procedures used; **(17025: 5.10.3.2.d)**

e) details of any environmental conditions during sampling that may affect the interpretation of the test results; **(17025: 5.10.3.2.e)**

f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned. **(17025: 5.10.3.2.f)**

5.5.10.4 Calibration certificates

5.5.10.4.1 In addition to the requirements listed in 5.5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results: **(17025: 5.10.4.1)**

a) the conditions (e. g. environmental) under which the calibrations were made that have an influence on the measurement results; **(17025: 5.10.4.1.a)**

b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof; **(17025: 5.10.4.1.b)**

c) evidence that the measurements are traceable. **(17025: 5.10.4.1.c)**

5.5.10.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met. **(17025: 5.10.4.2)**

When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference. **(17025: 5.10.4.2)**

When statements of compliance are made, the uncertainty of measurement shall be taken into account. **(17025: 5.10.4.2)**

5.5.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported. **(17025: 5.10.4.3)**

5.5.10.4.4 A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the client. This requirement may be superseded by legal regulations. **(17025: 5.10.4.4)**

5.5.10.5 Opinions and interpretations

When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report. **(17025: 5.10.5)**

5.5.10.8 Format of reports and certificates

The format shall be designed to accommodate each type of environmental test or calibration carried out and to minimize the possibility of misunderstanding or misuse. **(17025: 5.10.8)**

5.5.10.9 Amendments to test reports and calibration certificates

When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces. **(17025: 5.10.9)**